Research article

Breathing-synchronised electrical stimulation of the abdominal muscles in patients with acute tetraplegia: A prospective proof-of-concept study

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Objective: To examine whether, by enhancing breathing depth and expectoration, early use of breathing-synchronised electrical stimulation of the abdominal muscles (abdominal functional electrical stimulation, AFES) is able to reduce pulmonary complications during the acute phase of tetraplegia.
Design: Prospective proof-of-concept study.
Setting: Spinal cord unit at a level 1 trauma center.
Method: Following cardiovascular stabilisation, in addition to standard treatments, patients with acute traumatic tetraplegia (ASIA Impairment Scale A or B) underwent breathing-synchronised electrical stimulation of the abdominal muscles to aid expiration and expectoration. The treatment was delivered in 30-minute sessions, twice a day for 90 days. The target was for nine of 15 patients to remain free of pneumonia meeting Centers for Disease Control and Prevention (CDC) diagnostic criteria.
Results: Eleven patients were recruited to the study between October 2011 and November 2012. Two patients left the study before completion. None of the patients contracted pneumonia during the study period. No complications from electrical stimulation were observed. AFES led to a statistically significant increase in peak inspiratory and expiratory flows and a non-statistically significant increase in tidal volume and inspiratory and expiratory flow. When surveyed, 6 out of 9 patients (67%) reported that the stimulation procedure led to a significant improvement in breathing and coughing.
Conclusion: AFES appears to be able to improve breathing and expectoration and prevent pneumonia in the acute phase of tetraplegia (up to 90 days post-trauma). This result is being validated in a prospective multicentre comparative study.

Keywords: Acute traumatic tetraplegia, Functional electrical stimulation, Motor training of abdominal muscles, Airway complications, Pneumonia

Introduction

Pneumonia is one of the most frequent complications in the immediate (up to 5 days) and acute (up to 4 months) post-trauma periods following traumatic spinal cord injury (SCI).[1] During initial treatment, prevalence may be as high as 80%.[1–6] This high rate of pulmonary infection is the result of different factors, including reduced respiratory function and expectoration caused by tetraplegia, atelectasis, diminished muscle strength with acute trauma and rapid deconditioning, associated pain with diminished tidal volumes and ineffective cough, plus often an associated lung contusion or hemorrhage. The extent of this reduction in respiratory function depends on the neurological level and the extent of motor function loss.[2,7]

The objective of interdisciplinary management of respiratory dysfunction is to improve respiratory function,

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DOI 10.1179/2045772315Y.0000000054

more effective coughing to assist removal of secretions and a reduction in secretion resulting from autonomic dysfunction.[8] There are many existing therapies for improving respiratory function in patients with tetraplegia.[3,9,10] One new approach is to aid breathing and expectoration using breathing-synchronised abdominal functional electrical stimulation (AFES). Initial studies have shown that AFES has a beneficial effect on respiratory function measures,[11–16] mechanical output in coughing,[16–18] weaning and tracheostomy removal.[16] Studies[11–18] have predominantly been carried out on patients with a chronic SCI. To date, the clinical value of AFES in treating patients during the acute phase has not been examined.

This study aimed to develop an automated system for breathing-dependent stimulation of the abdominal musculature that would be simple to operate and be able to assist patients with SCI with breathing and coughing during the acute and chronic phases of their injury. After developing this system, a prospective proof-of-concept study was performed to examine whether this approach was able to reduce airway disease and pneumonia during the acute phase of a cervical SCI.

Method

A therapy system was developed in collaboration with the Technische Universität Berlin. The system was simple to operate and was able to stimulate both ventilated patients and patients breathing spontaneously during the acute phase. A prospective, single centre proof-of-concept study was carried out to examine the effect of AFES on the incidence of pulmonary complications in the initial period following a high spinal cord injury. AFES was embedded into our multimodal treatment concept. We started weaning discontinuously at daytime and if successfully, also at nighttime while monitoring capnometry and arterial blood gases. The weaning can be started at the ICU as well as at the peripheral ward via mobile home care ventilation. The weaning protocols were screened by medical doctors. All patients received physical and occupational therapy once a day. The study was approved by the Charité ethics committee (EA1/211/10) in December 2010. The study was performed in accordance with the criteria set out in the Declaration of Helsinki.

Subjects

Criteria for inclusion in the proof-of-concept study were: patients of either sex aged from 18 to 70, an acute isolated traumatic spinal cord injury up to 6-weeks post-trauma with a neurological level of C4–C8 with complete motor function loss (ASIA Impairment Scale A or B). The ASIA Impairment Scale (AIS) was modified in accordance with the revised 2011 version of the international standards for neurological classification of spinal cord injury.[19] Details of neurological classification and criteria are given in Table 1. Exclusion criteria were acute pneumonia, existing lung disease (eg, grade I-IV chronic obstructive pulmonary disease), cardiac insufficiency (New York Heart Association grade II-IV), a progressive disease (tumour, MS, etc.), BMI over 35, inability to place abdominal electrodes, implants which could interfere with electrical stimulation and lack of patient consent. Exclusion criteria did not include other pre-existing diseases affecting respiration. The listed conditions in Table 2 are the associated conditions in the subject patients in total. A multimodal or medical treatment of nicotine or alcohol abuse was rejected in both cases (Table 2).

Table 1 Neurological characteristics

	N	AIS A	AIS B
NL C4	5	3	2
NL C5	4	4	0
NL C6	0	0	0
NL C7	0	0	0
NL C8	0	0	0
Motor score (mean ± SD)	9	10 ± 10	20 ± 6
Sensory score (mean ± SD)	9	67 ± 39	78 ± 34

NL: neurological level AIS: ASIA Impairment Scale[19]; motor score = maximum 100 points; sensory score = pin prick score + light touch score = maximum 224 points.

Development and design of the FES system

The FES system was based on an 8-channel stimulator (RehaStim2, Hasomed GmbH, Magdeburg, Germany), to which was added an application module for functional electrical stimulation of the abdominal muscles (Fig. 1).

To enable the stimulator to synchronise stimulation with breathing, interfaces to a number of ventilators (Evita Infinity, Drägerwerk AG & Co. KGaA, Lübeck, Germany and Elisée™ 150 ResMed Corp, San Diego, CA, USA) and a spirometer (MicroLab MK8, CareFusion Corp., San Diego, CA, USA) were implemented. For patients who no longer required

Table 2 Pre-existing diseases affecting respiration

Secondary medical conditions	*n*
Hypertension	3
Diabetes	3
Actual smoking	1
Ankylosing spondylitis	1
Actual alcohol abuse	1
Hypothyroidism	1
Hepatitis	1

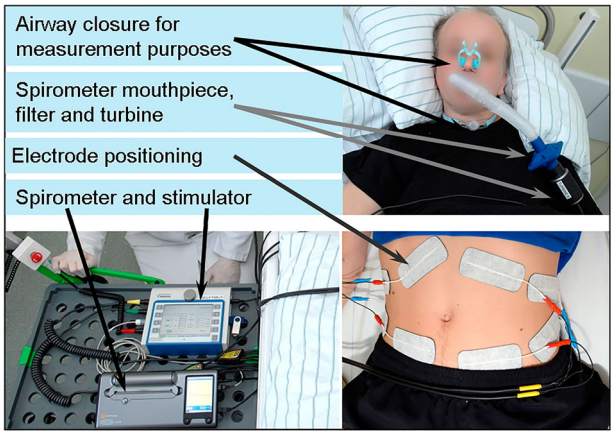


Figure 1 Electrode placement and device setup during stimulation.

mechanical ventilation, the spirometer was used to record and analyse respiratory function measures (e.g. respiratory flow and volume) via the patient's tracheostomy tube or face mask. Without modifying ventilator settings or function, respiratory phases were determined in real time to enable breathing-synchronised stimulation of the accessory muscles of respiration. The stimulation system is able to operate with invasive and non-invasive ventilation and with spontaneous breathing.

The abdominal muscles were stimulated during expiration and during the expiratory phase of coughing. The maximum stimulation current used was 126 mA and the maximum pulse duration 500 µs. Pulse charge—the product of current and pulse duration—was selected as a configurable unit of stimulation intensity. The current and pulse duration were varied in tandem such that the ratio of current to pulse duration remained constant. The device allows the user to set stimulation intensity as a percentage of the maximum possible pulse charge. The tolerable stimulation intensity (TSI) was determined weekly for each patient before commencing treatment. For patients with sensation in the stimulated area, TSI was set to the maximum tolerable pain level. Where there was no sensation in the stimulated area, TSI was determined on the basis of the visible amplitude of muscle contractions and, depending on sensation, maximum tolerable visceral pain. Pulses were delivered at a frequency of 30 Hz. Abdominal muscle stimulation was carried out using 4 pairs (Fig. 1) of flexible, reusable surface electrodes (4 × 9 cm, Hasomed GmbH, Magdeburg, Germany).

Stimulator functionality included a simple patient management system and a standardised training programme. The training programme consisted of phases of breathing-synchronised stimulation during expiration at 60% TSI and during expectoration at 100% TSI and phases with no stimulation (0% TSI). The phases with no stimulation served as recovery periods for the stimulated muscles (Fig. 2).

Performing abdominal FES in patients with acute tetraplegia

During the study, AFES was performed twice daily from Monday to Friday for 90 days, with at least 7 treatment sessions per week. Patients were examined by a doctor prior to each treatment session to check that it was appropriate to perform the procedure. The stimulation procedure was performed by a study nurse under medical supervision.

Each treatment session consisted of two stimulation cycles. A stimulation cycle consisted of a 10-minute period in which the abdominal muscles were trained by applying stimulation at 60% of TSI during expiration, followed by a 3-minute lung clearance phase in which the patient was asked to cough and stimulation at 100% of TSI was applied during coughing. A 3-minute break was taken before the second stimulation cycle to allow the muscles to recover. The second stimulation cycle was then performed (Fig. 2). In the study context, the treatment sessions took up a total of two hours per day. To enable integration into the ward routine, a set weekly timetable was produced in conjunction with the nursing staff. Suitable rest periods of up to 60 minutes were scheduled for patients after FES.

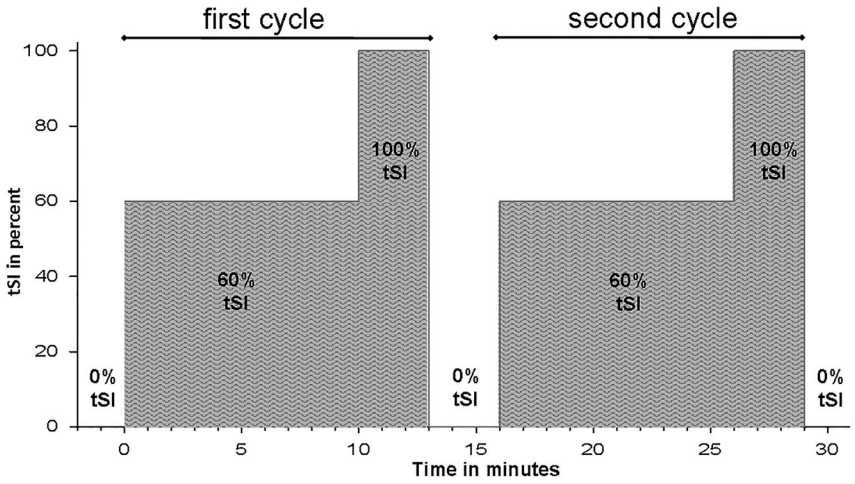
Study endpoints

The primary endpoint was a reduction in pulmonary complications, specifically pneumonia meeting CDC diagnostic criteria.[20] Sample size was determined on the basis of historical studies which found that up to 70% of patients with paraplegia suffer from respiratory complications during the acute phase of their illness.[21] FES treatment should aim to reduce this to less than 50%. Assuming a (two-sided) level of significance of 5% and a power of 80%, the required sample size was estimated at 15. 9 out of 15 patients would then be expected to remain pneumonia-free whilst receiving the stimulation intervention.

As a secondary endpoint, the study looked at whether AFES improved respiratory function and expectoration, and thus resulted in a reduction in weaning time, a reduction in the number of extubation attempts or tracheotomies or a reduction in length of stay on the intensive care unit.

Data recording and analysis

Patients were screened on admission to our facility to see whether they met the inclusion and exclusion criteria.



	Tidal volume [L]		Tidal volume [L]		CPF [L/min]		Tidal volume [L]		Tidal volume [L]		CPF [L/min]		Tidal volume [L]	
	0% tSI		60% tSI		100% tSI		0% tSI		60% tSI		100% tSI		0% tSI	
	first day	last day	first day	last day	first day	last day	first day	last day	first day	last day	first day	last day	first day	last day
mean	0.588	0.637	0.587	0.646	47.8	73.9	0.579	0.625	0.571	0.662	55.7	86.2	0.507	0.677
median	0.569	0.683	0.501	0.640	44.0	81.0	0.409	0.553	0.411	0.676	53.0	85.0	0.390	0.650
minimum	0.236	0.243	0.243	0.128	34.0	12.0	0.256	0.141	0.246	0.151	33.0	14.0	0.212	0.106
maximum	1.304	1.590	1.348	1.521	105.0	139.0	1.228	1.508	1.248	1.689	76.0	149.0	1.115	1.743
SEM	0.347	0.482	0.330	0.433	22.1	39.3	0.318	0.434	0.312	0.475	16.0	40.1	0.285	0.502
n	7	8	9	9	9	9	9	9	9	9	9	9	9	9
p-value	0.61		0.44		0.17		0.51		0.37		0.03*		0.31	

Figure 2 Stimulation cycles, tidal volume and cough peak flow.

To exclude pneumonia (assessed according to CDC criteria), a clinical examination, laboratory tests and an X-ray of the thorax were carried out. The tests were carried out and assessed by physicians who were not involved in the study.

During stimulation, relevant stimulation and respiratory function measures were recorded by the RehaStim2 stimulator (Hasomed GmbH, Magdeburg, Germany), stored in a record file and then transferred to an external USB drive for further analysis. Automated recording enabled the effect of stimulation on respiratory function measures—duration, volume and peak inspiratory and expiratory flow—to be continuously recorded. In addition, temperature, blood pressure, pulse rate and respiration rate were recorded daily and CRP and leucocytes measured weekly over the course of the study.

To evaluate acceptance of AFES, patients were surveyed using a standardised questionnaire every 14 days. The patients underwent a follow-up examination 3 and 6 months after completion of AFES treatment. The examination recorded key follow-up parameters and included a questionnaire about the study.

Statistics

Data are presented as means ± standard deviation (SD). The key criterion for stratification was the occurrence of pneumonia. Descriptive analysis was based on means, medians, deviations, minima and maxima. Statistical significance was set at $P < 0.05$. Prognostic values (e.g. whether the patient was still tracheotomised on discharge) were subsequently tested using logistic regression.

Results

Subjects

Between October 2011 and July 2012, a total of 11 patients were recruited to the study, of whom nine completed the study. One patient terminated their involvement in the study for personal reasons and one patient was transferred abroad before the end of the study. 9 patients were male (82%), 2 patients were female (18%). The average age was 50.6 (range 23–78). A summary of relevant clinical data on patients included into the study is given in Table 3. 10 of 11 spinal cord injuries were treated surgically (4 single segment (40%), 6 multiple segment (60%)), primarily using a ventral (80%, $n = 8$) or dorsal (20%, $n = 2$) approach. A second surgical intervention was required in 5 cases (50%), in 4 cases (80%) for planned counter-stabilisation of the spinal fracture and in one case (20%) due to complications arising after the initial operation.

Two of 9 patients had an autonomic dysreflexia, which we treated with Botox. One of these patients additionally received a sacral deafferentation according

Table 3 Subject characteristics

	N	Minimum	Maximum	Mean	SD
Age (years)	9	26	68	52.7	18.2
Height (m)	9	1.60	1.86	1.81	0.08
Weight (kg)	9	52.0	112.0	86.6	14.1
BMI (kg/m^2)	9	23.4	32.7	26.3	3.1

BMI: body mass index; SD: standard deviation

to Sauerwein with implantation of an anterior root stimulator referring to Brindley. However, the patient could not tolerate the stimulation, so that it is no longer active.

All patients were able to breath spontaneously without the aid of a ventilator during the treatment sessions. Patients were recruited to the study between 10 and 40 days after their accident (26 ± 10 days). The wide range was due to the need to properly explain the study to patients and to allow adequate time for patients to consider whether they wished to take part. This period was also extended by the fact that some patients were transferred from other hospitals (4 patients, 11 ± 7 days) and some had had pneumonia meeting CDC diagnostic criteria (3 patients, 30 ± 10 days) (Table 4).

Stimulation parameters

The maximum current applied was 126 mA, the maximum pulse duration 500 μs. 2 of 11 patients were able to perceive stimulation to the abdominal region (AIS B). In these patients, the mean initial stimulation current was 25 ± 3 mA, the mean initial pulse duration 199 ± 87 μs, the mean stimulation current at the end of the study 45 ± 9 mA and the mean pulse duration at the end of the study 280 ± 70 μs. In the remaining patients (AIS A), the mean initial stimulation current was 55 ± 21 mA, the mean initial pulse duration 245 ± 98 μs, the mean stimulation current at the end of the study 85 ± 34 mA and the mean pulse duration at the end of the study 337 ± 135 μs. Individual values are shown in Fig. 3.

Pneumonia

3 patients (27%) suffered episodes of pneumonia meeting CDC diagnostic criteria during their initial stay on the intensive care unit, prior to being recruited into the study (9 ± 2 days after their accident). These episodes were treated using resistance-appropriate or empirical antibiotic therapy. The average total cost of prescribed antibiotics per patient was €465. Univariate analysis did not identify any risk factors for the occurrence of pneumonia. It was not possible to perform multivariate analysis due to the group size.

None of the nine patients who completed the study contracted pneumonia meeting CDC criteria during the study period, allowing the study to be concluded before 15 patients had been recruited.

None of the patients contracted pneumonia in the 6 months after receiving FES treatment.

Respiratory function and expectoration

Comparison between first and last days

Over the course of the study, the stimulation procedure resulted in an increase in all respiratory function measures (tidal volume, inspiratory flow and expiratory flow). The increase in peak inspiratory and expiratory flow at 100% TSI was statistically significant (Fig. 2). This increase is evidence for the efficacy of AFES and

Table 4 Subject time table

	Duration after trauma until [d]					
Patient No.	1st Spine surgery	Inpatient admission	Tracheostoma	Diagnosis of Pneumonia	Study inclusion	AFES (d)
1	0	0	–	–	10	90
2	2	11	–	–	16	90
3	0	3	7	–	16	90
4	0	0	9	6	19	90
5	0	0	6	–	20	90
6	1	0	8	–	31	90
7	0	23	9	–	35	90
8	3	0	11	10	35	90
9	0	0	3	10	38	90
Drop out 1	0	0	7	–	40	21
Drop out 2	–	8	10	–	23	42

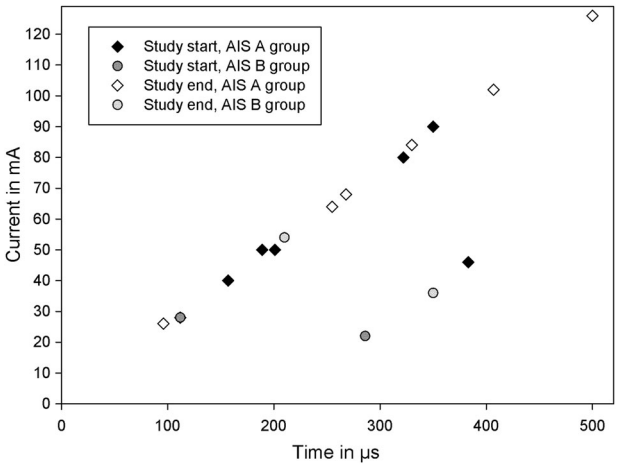


Figure 3 Stimulation intensity at the start and end of the study.

can be considered indicative of a training effect on the accessory muscles of expiration stimulated by the device.

Comparison of stimulation intensity

We examined whether different stimulation intensities (0% of TSI during the rest phase, 60% of TSI during the training phase and 100% of TSI for lung clearance) affected respiratory function measures. We analysed mean measurement values for all patients, averaged over two treatment sessions performed on the same day. We found that AFES led to a reduction in the duration of inspiration and expiration and an increase in tidal volume and cough peak flow. A significant difference of the Cough Peak Flow (CPF) between the first and the last day of AFES could be substantiated in the regression analysis (Fig. 2).

Comparison between the two stimulation cycles within a treatment session

We investigated whether repeated treatment sessions led to exhaustion of the abdominal musculature by comparing the first and second stimulation cycles. Differences in tidal volume, inspiratory and expiratory flow and cough peak flow were small and not statistically significant. We were not able to demonstrate any exhaustion of the musculature during the second stimulation cycle.

Tracheotomy and weaning

Tracheotomy was performed 8 ± 2 days after ventral spinal surgery in 82% of cases ($n = 9$). The weaning process in these patients was discontinuous, i.e. they switched between gradually lengthening periods of spontaneous breathing, interspersed with recovery periods during which they were mechanically ventilated. The length of these periods was determined individually for each patient. 78 percent of this subgroup ($n = 7$) weaned successfully at the first attempt. One patient experienced dyspnoea (but not pneumonia), and required a second attempt at weaning. This patient weaned successfully at the second attempt. In 2 cases AFES was terminated after 21 respectively 42 days. On concluding the study, one patient was still undergoing intermittent ventilation and three patients (22%) still had a tracheostoma for suctioning. Timings are shown in Fig. 4.

Univariate analysis did not identify any risk factors for tracheostomy. The number of observations was insufficient for multivariate analysis. Cox regression analysis did not find any statistically significant effect of individual variables (age, BMI, AIS, spinal level affected, number of pre-existing comorbidities, number of additional injuries, number of secondary medical conditions, number of ICU stays and pneumonia incidence prior to recruitment into the study) on duration of weaning.

Time in intensive care and hospital units

The average time spent on the ICU was 24 ± 11 days. One day after the transfer from ICU to the spinal unit, 1 patient (11%) required readmission to ICU due to pulmonary insufficiency. On this second ICU admission, the patient remained on the unit for 20 days. During this period AFES was continuosly carried out. Total length of hospital admission was 138 ± 47 days.

There was a statistically significant correlation between length of admission to the intensive care unit and the number of recorded comorbidities ($P = 0.048$).

Complications caused by stimulation

None of the patients experienced serious complications during or after stimulation which required them to stop receiving the stimulation intervention. Slight skin reddening at the end of the stimulation procedure was observed in a small number of cases. Patients reported no adverse effects during or after stimulation. New symptoms, such as an increase in spasticity or an effect on bowel evacuation, were not observed. No study-related complications were observed at the 3- or 6-month post-intervention follow-ups.

Patient survey

In addition to collection of objective data, a patient survey using a 5-point scale (not at all, a little, moderately, significantly, totally) was taken on the first and last days on which the stimulation treatment was performed. The questions were "Do you have the feeling that abdominal stimulation enables you to breathe better?," "Do you find abdominal stimulation unpleasant?" and "Do you feel that abdominal stimulation restricts you in your normal daily activities?".

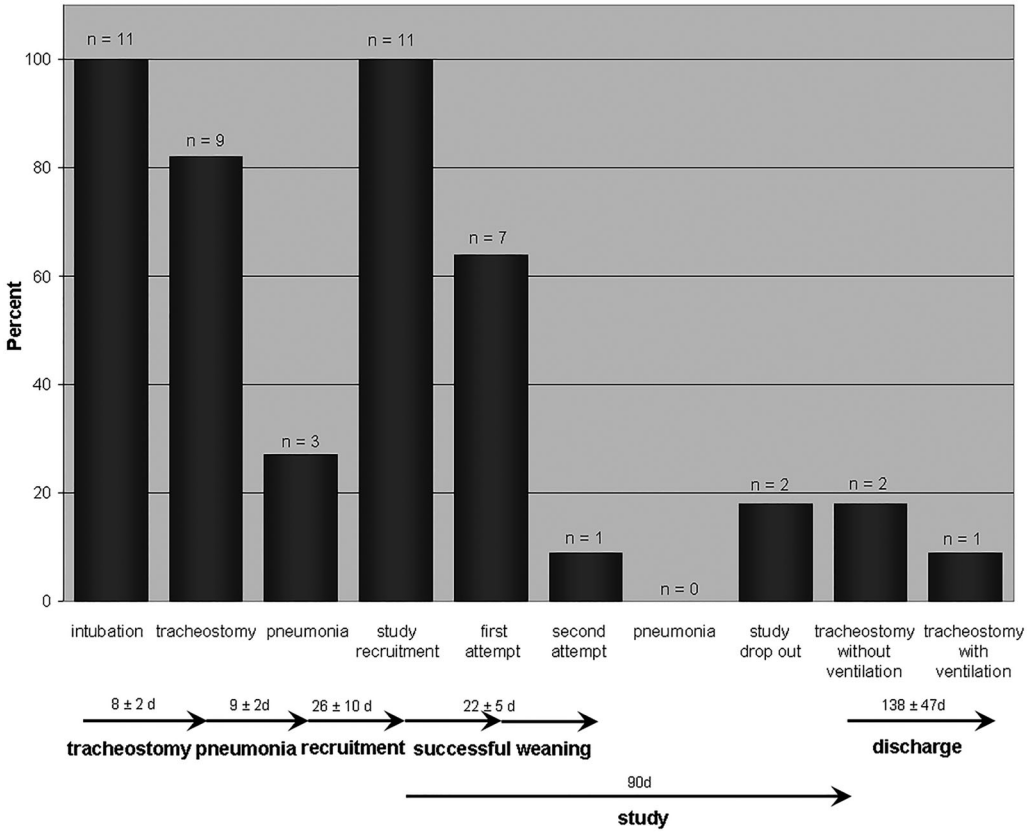


Figure 4 Study plan.

Between the first and last days on which the stimulation treatment was performed, the number of patients reporting that abdominal stimulation resulted in a moderate to total improvement in breathing rose from 22% (2 patients) to 67% (7 patients). Seven patients (67%) reported that abdominal stimulation was not at all or a little unpleasant.

Responses to the question on restriction of everyday activities reflected the time required to carry out the procedure. Just 1 patient (11%) described the procedure as "moderately to significantly restrictive" on the first day of treatment, rising to 4 patients (44%) on the final day of treatment.

Using a Wilcoxon test, no statistically significant differences between responses on the first and last days of treatment were found.

Discussion

The goal of this study was to examine the clinical value of AFES in the management of acute tetraplegia. This required the development of a stimulation system that was able to deliver breathing-synchronised stimulation both in patients undergoing mechanical ventilation and in patients breathing spontaneously, either nasally or via a cannula. By continuously reading data from the ventilator or a spirometer, the system developed during the study was able to meet this requirement and algorithms able to deliver breathing-synchronised stimulation were implemented on the device. Device operation and the procedure for delivering the stimulation treatment were designed to allow the treatment, in normal clinical practice, to be delivered by auxiliary staff. No complications occurred during the stimulation procedure. Gollee *et al.*[16] have previously demonstrated the benefits of AFES in a study on 4 patients. They found that AFES increased tidal volume by up to 71% and cough peak flow by up to 54%. Our study found a statistically significant improvement in peak inspiratory and expiratory flow at 100% of tolerable stimulation intensity. We also observed an improvement in tidal volume, though this was not statistically significant. At the end of the study 6 patients (67%) reported that the stimulation procedure resulted in a moderate to total improvement in breathing.

No recommendations regarding the current to be applied during AFES are available at present. In this study, the upper limit for the applied current was set at 126 mA, with a pulse duration of 500 μs. The TSI was adjusted individually for each patient and was comparable with values from other published studies.[11–17,22–24]

Initial stimulation intensity was 55% lower in patients classified as AIS B than in patients classified as AIS A. The increase in stimulation intensity over the course of the study was comparable in these two sets of patients, but the maximum stimulation intensity at the end of the study in patients classified as AIS B was still lower than the maximum stimulation intensity at the start of the study in patients classified as AIS A. The stimulation intensity tolerated by a patient depended on the degree of abdominal sensation. Clinical outcomes were the same in both groups. Based on our study, we consider that the therapeutic range for applied stimulation intensity for coughing is 25–85 mA, 199–337 μs and a frequency of 30 Hz. The therapeutic range for breathing is 60% of that for coughing.

Further studies will be required to determine the optimum frequency of AFES application.[11–13,17,25] Our study required a minimum of 7 treatment sessions and not more than three treatment-free days per week, to ensure that there was not too great a diminution in the training effect on the abdominal musculature and the effect on respiration.

A stimulation cycle lasted for 13 minutes and was followed by a second cycle. Analysis of respiratory function did not find evidence of muscular exhaustion during the second stimulation cycle. The use of longer stimulation periods would therefore appear to be feasible. Delivering 2 treatment sessions for initial treatment of traumatic SCI per day did, however, in practice require the use of a daily timetable. At the end of the study, 44% of patients in our study reported that the treatment moderately or significantly restricted their daily activities. The possibility of using AFES to support breathing at night was discussed, but not examined further.

Pneumonia

Patients were not recruited to the study until between 10 and 38 days post-trauma. Time of recruitment was affected by factors including the ability of patients to give consent, primary spinal surgical care carried out in some cases in other hospitals and treatment for pneumonia. 3 patients (33%) contracted pneumonia meeting CDC diagnostic criteria[20] prior to recruitment to the study (between 6 and 10 days post-trauma). These patients were not able to be recruited to the study before contracting pneumonia, as they were not in a position to consent to taking part in the study. Those pneumonia were treated appropriate to bacterial resistancy after microbiological examination of the tracheal secretion. A complete clinical and biochemical healing of pneumonia was not defined as a criterion for exclusion, because those patients beared the same risk of pneumonia as patients without previous pneumonia. The incidence of pneumonia in our study was, however, lower than that in other studies,[1–6,26] where incidences of up to 80% have been reported. The low incidence in our study is due to the fact that, between commencing AFES and the 6-month follow-up, not a single case of pneumonia was observed. The pneumonia rate in a comparable previous group of patients (traumatic SCI, AIS A-B, neurological level C4–8)[26] was 54%. The reduction in pneumonia rates compared to the previous group, who, other than not receiving AFES treatment, received comparable treatment, supports the hypothesis that the change in respiratory function resulting from more intense breathing and coughing as a result of the use of AFES has a positive effect on pneumonia incidence.

Secondary study objectives

The initial tracheotomy was carried out in accordance with criteria for patients with neurological level C4–8 after Seidl *et al.*[21] The figures for tracheotomies performed (78%), patients with a tracheostomy (33%) and patients who were undergoing intermittent ventilation (11%) at the conclusion of the study were comparable with those from a retrospective study.[26] We did not observe the positive effect of abdominal FES on tracheostomy tube removal described by Lee *et al.*[25] in a case study.

In comparison with a study involving comparable patients by Liebscher *et al.*[26] our patients had shorter weaning times (75 ± 49 days/25 ± 8 days), fewer weaning attempts (successfully weaned at the first attempt 45%/55%), but a longer stay on the intensive care unit (21 ± 32 days/24 ± 11 days). The reason for the longer stay on the intensive care unit was that weaning was performed on the intensive care unit due to the greater level of monitoring on the unit. It was not possible to assess the duration of weaning in this study, as most patients were fully weaned prior to recruitment to the study.

Complications

Temporary skin reddening following the stimulation procedure occurred in a small number of cases. Patients with abdominal sensation did not report significant pain during or after stimulation. No exacerbation of specific symptoms, such as spasticity or an effect on bowel evacuation, was observed during or after stimulation. The improvement in bowel evacuation observed by Bartova *et al.*[12] was not reproduced in this study. We did not investigate other effects of stimulation

(cardiovascular, bowel evacuation). These should be investigated in any further studies.

Limitations of the study

Limiting factors in our study were the number of patients, the lack of a control group and the use of retrospective controls, particularly when the trials are small and the population are very heterogeneous. The paucity of studies on abdominal FES did not allow a suitable maximum current and pulse duration for this study to be identified independently. The maximum stimulation intensity was therefore determined individually based on local pain in the stimulated area for patients with abdominal sensation and visceral pain and amplitude of muscle contractions in patients with no abdominal sensation.

Conclusion

A key problem in treating patients with a C4–C8 spinal cord injury with complete loss of motor function (AIS A, B) is securing the airway and long-term prevention of pulmonary complications. The objective of this study was to develop and evaluate breathing-synchronised electrical stimulation of abdominal accessory muscles of respiration (AFES). AFES is designed to reduce pulmonary complications, enhance respiratory function and support coughing. In this proof-of-concept study a small number of cases showed no pneumonia according to the CDC criteria during AFES intervention. By enhancing breathing and coughing, AFES led to an increase in respiratory function measures (duration, volume, peak inspiratory and expiratory flow). There was a positive effect on the secondary end points "effect of AFES on weaning," "reduced length of admission to the intensive care unit" and "reduced morbidly and mortality," but the small sample size meant that it was not possible to definitively analyse these endpoints. No significant complications occurred during or after FES treatment. The AFES treatment procedure developed for and examined in this study now needs to be examined in a randomised, multicentre study.

Acknowledgments

We thank Maryna Verba for compiling the bibliometric data.

Disclaimer statements

Contributors All authors were actively involved in the study. ROS initiated and led the study. TL, TS, RS, EP, AN and AE were involved in planning, performing and analysing the study.

Funding This study was funded by the German Statutory Accident Insurance (DGUV, registration number FR 182 ukb).

Conflicts of interest All authors declare that they have no financial or professional conflicts of interest.

Ethics approval The study was approved by the Charité ethics committee (EA1/211/10) in December 2010. The study was performed in accordance with the criteria set out in the Declaration of Helsinki.

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